

HCFA under section 1833(a)(1)(A) of the Act and part 417, subpart U, of this chapter.

(3) An organization that is receiving payments on a prepaid basis for the enrollees through a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b–1 note).

(4) A qualified health maintenance organization (within the meaning of section 1310(d) of the Public Health Service Act).

(d) *Services furnished in an ambulatory surgical center (ASC) or end stage renal disease (ESRD) facility, or by a hospice if payment for those services is included in the ASC rate, the ESRD composite rate, or as part of the per diem hospice charge, respectively.*

**§ 411.356 Exceptions to referral prohibitions related to ownership or investment interests.**

For purposes of § 411.353, the following ownership or investment interests do not constitute a financial relationship:

(a) *Publicly traded securities.* Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that may be purchased on terms generally available to the public and that meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(1) They are either—

(i) Listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis; or

(ii) Traded under an automated inter-dealer quotation system operated by the National Association of Securities Dealers.

(2) In a corporation that had—

(i) Until January 1, 1995, total assets at the end of the corporation's most recent fiscal year exceeding \$100 million; or

(ii) Stockholder equity exceeding \$75 million at the end of the corporation's

most recent fiscal year or on average during the previous 3 fiscal years.

(b) *Mutual funds.* Ownership of shares in a regulated investment company as defined in section 851(a) of the Internal Revenue Code of 1986, if the company had, at the end of its most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding \$75 million.

(c) *Specific providers.* Ownership or investment interest in the following entities:

(1) A laboratory that is located in a rural area (that is, a laboratory that is not located in an urban area as defined in § 412.62(f)(1)(ii) of this chapter) and that meets the following criteria:

(i) The laboratory testing that is referred by a physician who has (or whose immediate family member has) an ownership or investment interest in the rural laboratory is either—

(A) Performed on the premises of the rural laboratory; or

(B) If not performed on the premises, the laboratory performing the testing bills the Medicare program directly for the testing.

(ii) Substantially all of the laboratory tests furnished by the entity are furnished to individuals who reside in a rural area. Substantially all means no less than 75 percent.

(2) A hospital that is located in Puerto Rico.

(3) A hospital that is located outside of Puerto Rico if one of the following conditions is met:

(i) The referring physician is authorized to perform services at the hospital, and the physician's ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital.

(ii) Until January 1, 1995, the referring physician's ownership or investment interest does not relate (directly or indirectly) to the furnishing of clinical laboratory services.

**§ 411.357 Exceptions to referral prohibitions related to compensation arrangements.**

For purposes of § 411.353, the following compensation arrangements do not constitute a financial relationship:

(a) *Rental of office space.* Payments for the use of office space made by a

lessee to a lessor if there is a rental or lease agreement that meets the following requirements:

(1) The agreement is set out in writing and is signed by the parties and specifies the premises covered by the lease.

(2) The term of the agreement is at least 1 year.

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee, except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas.

(4) The rental charges over the term of the lease are set in advance and are consistent with fair market value.

(5) The charges are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(6) The agreement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

(b) *Rental of equipment.* Payments made by a lessee to a lessor for the use of equipment under the following conditions:

(1) A rental or lease agreement is set out in writing and signed by the parties and specifies the equipment covered by the lease.

(2) The equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee.

(3) The lease provides for a term of rental or lease of at least 1 year.

(4) The rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(5) The lease would be commercially reasonable even if no referrals were made between the parties.

(c) *Bona fide employment relationships.* Any amount paid by an employer to a physician (or immediate family member) who has a bona fide employment relationship with the employer for the provision of services if the following conditions are met:

(1) The employment is for identifiable services.

(2) The amount of the remuneration under the employment is—

(i) Consistent with the fair market value of the services; and

(ii) Except as provided in paragraph (c)(4) of this section, is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.

(3) The remuneration is provided under an agreement that would be commercially reasonable even if no referrals were made to the employer.

(4) Paragraph (c)(2)(ii) of this section does not prohibit payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or immediate family member of the physician).

(d) *Personal service arrangements.* (1) *General.* Remuneration from an entity under an arrangement to a physician or immediate family member of the physician, including remuneration for specific physicians' services furnished to a nonprofit blood center, if the following conditions are met:

(i) The arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.

(ii) The arrangement covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity.

(iii) The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.

(iv) The term of the arrangement is for at least 1 year.

(v) The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market

value, and, except in the case of a physician incentive plan, is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(vi) The services to be furnished under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(2) *Physician incentive plan exception.* In the case of a physician incentive plan between a physician and an entity, the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account directly or indirectly the volume or value of any referrals or other business generated between the parties, if the plan meets the following requirements:

(i) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services furnished with respect to a specific individual enrolled in the entity.

(ii) In the case of a plan that places a physician or a physician group at substantial financial risk as determined by the Secretary under section 1876(i)(8)(A)(ii) of the Act, the plan complies with any requirements the Secretary has imposed under that section.

(iii) Upon request by the Secretary, the entity provides the Secretary with access to descriptive information regarding the plan, in order to permit the Secretary to determine whether the plan is in compliance with the requirements of paragraph (d)(2) of this section.

(3) Until January 1, 1995, the provisions in paragraph (d)(1) and (2) of this section do not apply to any arrangements that meet the requirements of section 1877(e)(2) or section 1877(e)(3) of the Act as they read before they were amended by the Omnibus Budget Reconciliation Act of 1993 (Public Law 103–66).

(e) *Physician recruitment.* Remuneration provided by a hospital to recruit a physician that is intended to induce the physician to relocate to the geographic area served by the hospital in

order to become a member of the hospital's medical staff, if all of the following conditions are met:

(1) The arrangement and its terms are in writing and signed by both parties.

(2) The arrangement is not conditioned on the physician's referral of patients to the hospital.

(3) The hospital does not determine (directly or indirectly) the amount or value of the remuneration to the physician based on the volume or value of any referrals the physician generates for the hospital.

(4) The physician is not precluded from establishing staff privileges at another hospital or referring business to another entity.

(f) *Isolated transactions.* Isolated financial transactions, such as a one-time sale of property or a practice, if all of the conditions set forth in paragraphs (c)(2) and (c)(3) of this section are met with respect to an entity in the same manner as they apply to an employer. There can be no additional transactions between the parties for 6 months after the isolated transaction, except for transactions which are specifically excepted under the other provisions in §§ 411.355 through 411.357.

(g) *Arrangements with hospitals.* (1) Until January 1, 1995, any compensation arrangement between a hospital and a physician or a member of a physician's immediate family if the arrangement does not relate to the furnishing of clinical laboratory services; or

(2) Remuneration provided by a hospital to a physician if the remuneration does not relate to the furnishing of clinical laboratory services.

(h) *Group practice arrangements with a hospital.* An arrangement between a hospital and a group practice under which clinical laboratory services are provided by the group but are billed by the hospital if the following conditions are met:

(1) With respect to services provided to an inpatient of the hospital, the arrangement is pursuant to the provision of inpatient hospital services under section 1861(b)(3) of the Act.

(2) The arrangement began before December 19, 1989, and has continued in effect without interruption since then.

(3) With respect to the clinical laboratory services covered under the arrangement, substantially all of these services furnished to patients of the hospital are furnished by the group under the arrangement.

(4) The arrangement is in accordance with an agreement that is set out in writing and that specifies the services to be furnished by the parties and the compensation for services furnished under the agreement.

(5) The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of services is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(6) The compensation is provided in accordance with an agreement that would be commercially reasonable even if no referrals were made to the entity.

(i) *Payments by a physician.* Payments made by a physician—

(1) To a laboratory in exchange for the provision of clinical laboratory services; or

(2) To an entity as compensation for other items or services that are furnished at a price that is consistent with fair market value.

#### § 411.360 Group practice attestation.

(a) Except as provided in paragraph (b) of this section, a group practice (as defined in section 1877(h)(4) of the Act and § 411.351) must submit a written statement to its carrier annually to attest that, during the most recent 12-month period (calendar year, fiscal year, or immediately preceding 12-month period) 75 percent of the total patient care services of group practice members was furnished through the group, was billed under a billing number assigned to the group, and the amounts so received were treated as receipts of the group.

(b) A newly-formed group practice (one in which physicians have recently begun to practice together) or any group practice that has been unable in the past to meet the requirements of section 1877(h)(4) of the Act must—

(1) Submit a written statement to attest that, during the next 12-month pe-

riod (calendar year, fiscal year, or next 12 months), it expects to meet the 75-percent standard and will take measures to ensure the standard is met; and

(2) At the end of the 12-month period, submit a written statement to attest that it met the 75-percent standard during that period, billed for those services under a billing number assigned to the group, and treated amounts received for those services as receipts of the group. If the group did not meet the standard, any Medicare payments made for clinical laboratory services furnished by the group during the 12-month period that were conditioned upon the standard being met are overpayments.

(c) Once any group has chosen whether to use its fiscal year, the calendar year, or some other 12-month period, the group practice must adhere to this choice.

(d) The attestation must contain a statement that the information furnished in the attestation is true and accurate and must be signed by a group representative.

(e) A group that intends to meet the definition of a group practice in order to qualify for an exception described in §§ 411.355 through 411.357, must submit the attestation required by paragraph (a) or paragraph (b)(1) of this section, as applicable, to its carrier no later than 60 days after receipt of the attestation instructions from its carrier.

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#### § 411.361 Reporting requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, all entities furnishing items or services for which payment may be made under Medicare must submit information to HCFA concerning their financial relationships (as defined in paragraph (d) of this section), in such form, manner, and at such times as HCFA specifies.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply to entities that provide 20 or fewer Part A and Part B items and services during a calendar year, or to designated health services provided outside the United States.